

Claim Listing

This listing of claims will replace all prior versions, and listings, of claims in the present application.

1. (currently amended) A sustained-release pharmaceutical composition comprising granulocyte-colony stimulating factor (G-CSF), polyol:oil and a thickener, where said composition is prepared by a process which comprises:

(a) mixing a solution of G-CSF in a polyol [[-]] to form a G-CSF:polyol composition;

(b) suspending said G-CSF:polyol composition in a composition comprising a thickened oil as a thickener wherein the level of said polyol is in the range from 15%-30% by weight.

2. (currently amended) The pharmaceutical composition of Claim 1 wherein said polyol is a biocompatible polyol is selected from the group consisting of glycerol, erythritol, arabinose, xylose, ribose, inositol, fructose, galactose, maltose, glucose, mannose, and sucrose.

3. (currently amended) The pharmaceutical composition of Claim 1 wherein said oil of said polyol:oil is selected from the group consisting of sesame, castor, cottonseed, canola, saffron, olive, peanut, sunflower seed, a-tocopherol, Miglyol 812, and ethyl oleate.

8. ~~4.~~ (previously presented) The pharmaceutical composition of Claim ~~13~~⁴ wherein the thickener is aluminum monostearate.

9. ~~8.~~ (previously presented) The pharmaceutical composition of Claim ~~13~~⁴ wherein the thickener is white wax.

6-7. (canceled)

10. ~~8.~~ (currently amended) A process for preparing a sustained-release pharmaceutical composition ~~compositions~~ of G-CSF:polyol:oil which comprises:

(a) mixing a solution of G-CSF in a polyol to form a G-CSF:polyol composition;

(b) suspending said G-CSF:polyol composition in a composition comprising a thickened oil wherein the level of said polyol in said composition comprising a thickened oil suspension is in the range from 15%-30% by weight.

9-12. (canceled)

4. ~~13.~~ (currently amended) The pharmaceutical composition of Claim 1 wherein the thickener is selected from the group consisting of ~~fatty acids~~, polyvalent metal salts of organic acids, alcohols, waxes and high-viscosity oils.

5. ~~14.~~ (previously presented) The pharmaceutical composition of Claim 1 further comprising a stabilizer selected from the group consisting of a surfactant and an emulsifier.

6. ~~15.~~ (previously presented) The pharmaceutical composition of Claim 1 wherein the solution of G-CSF comprises a solvent selected from the group consisting of water and glycerol.

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11. ~~16.~~ (previously presented) The process of Claim ~~8~~ wherein the solution of G-CSF comprises a solvent selected from the group consisting of water and glycerol.

7. ~~17.~~ (previously presented) The pharmaceutical composition of Claim 1 wherein said thickened oil comprises hydrogenated vegetable oil.